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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/529,967 04/24/00 KORPELA

M 2328-117

EXAMINER

HM22/0223

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SISSON, B

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

02/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/529,967	Applicant(s) KORPELA ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 April 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 20) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-10, 16-19 in Paper No. 7, received 9 February 2001, is acknowledged. The traversal is on the ground(s) that neither the International Searching Authority nor the International Preliminary Examining Authority held that the claims lack unity of invention. This is not found persuasive because the holdings of the ISA or IPEA are not binding upon the USPTO.
2. Argument is also advanced in that the method of claim 1 encompasses embodiments found in claim 11, namely a vector and host cell that produces light in response to being cultured in the presence of tetracycline. This is not found persuasive for while claim 1 may have sufficient breadth so to encompass these embodiments, the method of claim 1 is not limited to just these embodiments. In light of the requirement of the Office to read the claims as broadly as is reasonably possible, the method of claim 1 has also been found to encompass any number of embodiments that are not recited in claim 11 or in claim 14. Accordingly, the subject application has not been found to have unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

### ***Drawings***

3. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action.

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However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

### *Specification*

4. The use of the trademark POLAROID has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of *E. coli* K-12/pTetLux1 and *E. coli* K-12/TetLuc1 to detect the presence of tetracycline in the presence of culture broth as well as in spiked limpec porcine serum, does not reasonably provide enablement for the detection of any and all levels of tetracycline in any type of sample, regardless of its heterogeneity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity

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of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*The Quantity of Experimentation Necessary*

The quantity of experimentation need is great, on the order of several man-years and then with little, if any, reasonable expectation of success.

*The Amount of Direction or Guidance Provided and The Presence or Absence of Working*

*Examples*

The amount of guidance provided is severely limited. As seen in Example 2, page 17 of the specification, a comparison was conducted between *E. coli* K-12/pTetLux1 and *E. coli* K-12/TetLuc1. In Example 3, (page 18, first paragraph) “fresh *E. coli* K-12/pTetLux1 were diluted 1:50 with 25 mM MES buffer in M9 minimal medium, pH 6.0. 100 µl bacterial suspension was added to microtiter plate wells containing 100 µl of pig serum spiked with different tetracyclines.” Example 4 (page 18, second paragraph), like that of Example 3, teaches the use of *E. coli* K-12/pTetLux1 in detecting the presence of tetracyclines in milk to which has been added EDTA. The specification does not teach how one of skill should proceed in the testing of samples such as “fish, meat, infant formula, eggs, honey, vegetables, serum, plasma, whole blood or the like” (claim 10). The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

“ [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue

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experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’).

\*\*\*\*\*

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. “It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (emphasis added)

While the specification has been found to provide limited guidance, such guidance does not extend to the full scope for which patent protection is being sought. Accordingly, it would require undue experimentation for one of skill in the art to practice the full scope of the claims. Applicant is urged to consider narrowing the scope of the claims to those embodiments adequately supported by the disclosure.

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*The Nature of the Invention*

The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re*

*Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

*The State of the Prior Art*

The state of the art is limited in the area of recombinant mechanisms for the detection of tetracyclines.

*The Relative Skill of Those in the Art*

The relative skill of those in the art that is most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry.

*The Breadth of Scope of the Claims*

The claims have sufficient breadth of scope so to encompass any number of constructs that can be used in the detection of any level of tetracycline. As presently worded, the claimed method places no limitation on (a) the type of media used for culturing the transformant; (b) the type of transformant used; (c) the heterogeneity of the sample; (d) what means are used to

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determine just which tetracycline is present; (e) what means, if any, are employed so to determine the quantity of each tetracycline present; and (f) the level of sensitivity of the assay.

In view of the breadth of scope of the claims now before the Office, the unpredictableness of the assay system, and the limited guidance provided, the level of effort needed to be exerted by the public in order to practice the full scope of the claimed method constitutes undue experimentation. Accordingly, applicant is again urged to consider adopting claims that more closely align the scope of the claims with the level of disclosure provided.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "especially antibiotic sensitive" in claim 8 is a relative term that renders the claim indefinite. The term "especially antibiotic sensitive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. Regarding claim 10, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).



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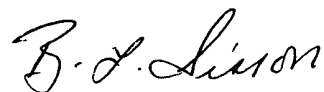
10. Regarding claim 9, the use of the trademark POLAROID renders the claim indefinite as the product represented by a trademark is subject to change without public notice.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1655

BLS  
February 21, 2001